Amendments to the Drawings:

Cancel Figure 1 and substitute therefor the new Figure 1 enclosed.

REMARKS/ARGUMENTS

Petition is hereby made under the provisions of 37 CFR 1.136(a) for an extension of two months of the period for response to the Office Action. Authorization to charge the fee to our deposit account is enclosed.

Applicants gratefully acknowledge the indicated allowance of claims 12 to 15.

The Examiner objected to the drawings on the basis that the newly-submitted drawings are not as originally filed. In particular, the Examiner noted that there is no data in newly-submitted Figure 1 charting for CLP-178, whereas the original drawings contained such data. Figure 1 submitted herewith corrects this defect.

The Examiner maintained rejection of claims 1 and 4 to 11 under 35 USC 112, first paragraph, as failing to comply with the enablement requirement. In this regard, the Examiner considered that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons set forth in the previous Office Action. Reconsideration is requested for the reasons set forth herein.

In the prior Office Action, the Examiner indicated that the basis for the rejection was that, while acknowledging that applicants assertion that applicants do not promise that the procedure of the invention is a vaccination procedure against HIV and that applicants do not demonstrate the same:

> "...However this does not evade the obvious fact that the instantly claimed invention reads on a vaccine method that is used to treat and/or prevent HIV infection through the generation of HIV-specific cytotoxic T-cell response in a host."

The Examiner repeats such assertion in the Final Action.

The applicants repeat that, in considering compliance of claims with the provisions of 35 USC 112, first paragraph, the Examiner is required to consider what is actually claimed. What is actually claimed in the present invention is a method of generating HIV-specific cytotoxic T-cell responses in a host and **not** a vaccine method of that is used to treat and/or prevent HIV infection, as asserted by the Examiner in the above quotation from the prior Office Action.

Applicants invention is illustrated by using peptides which correspond to a portion of the hepatitis B virus nucleocapsid antigen and certain lipopeptides derived from a REV portion of HIV-1.

The Examiner takes the view in the Final Action that:

> "The issue at hand is that the claimed method, in view of the specification, reads on a method of treating or preventing HIV infection."

However, that is not what the plain language of the claim says. Claim 1 claims:

> "A method of generating an HIV-specific cytotoxic T-cell (CTL) response in a host possessing MHC class I HLA A2 molecules"

Nothing more, nothing less. The Examiner considers:

> "while this [i.e. the alleged method of treating or preventing HIV infection] is not explicitly recited in the claims."

Surely the test is what the claim language explicitly states. The Examiner goes on to state:

> "... claimed subject matter is interpreted in view of the disclosure."

The Examiner cites no basis in law for interpretation of claim language by reference to the disclosure when the claimed subject matter is explicitly defined.

The Examiner asserts in the Final Action that:

> "The biological activity that can be ascertained by the implementation of the claimed method is not readily apparent in the claims."

The biological activity is stated, namely generation of a HIV-specific CTL response in a host. If the claim language is indefinite, as seems to be suggested by the Examiner then the rejection is more properly made under 35 USC 112, second paragraph, and not 35 USC 112, first paragraph.

The applicants acknowledge the passages of the disclosure to which the Examiner refers. However, we categorically disagree with the conclusion drawn by the Examiner in the Final Action:

> "... the Examiner considers that the intended purpose of the claimed invention is directed at a protocol for the treatment and/or prevention of HIV."

Even if this were the case, the Examiner does not explain why this means that applicants claims fail to comply with 35 USC 112, first paragraph.

The Examiner goes on to state in the Final Action that:

> "Therefore, in view of what is currently presented in the claims, in the light of the disclosure...., it is concluded that the breadth of the claimed invention encompasses an *in vivo* vaccine method that is used to treat, prevent, or inhibit the progression of HIV infection in humans and non-human animals by generating an HIV-specific CTL response in the host."

As claimed above, the Examiner's resort to the disclosure for interpretation of the scope of claim language which is clear on its face is improper and the conclusion drawn flies in the face of the plain language of the claims.

The applicants do not claim an *in vivo* vaccine method that is used to treat, prevent or inhibit the progression of HIV infection. Applicants data does not demonstrate any such result. The plain language of claim 1 claims a method of generating, in a host, an HIV-specific cytotoxic T-cell response in a host possessing MHC class I HLA A2 molecules and applicants data demonstrates the generation of such CTL response.

In any event, even if the Examiner's position were sound, which, it is submitted, it is not, then the Examiner has not explained why the "*in vivo* vaccine method" does not comply with 35 USC 112, first paragraph, with respect to enablement. If, arguendo, claim 1 is interpreted to cover the method asserted by the Examiner, the claim nevertheless is enabled, since applicants data supports such claims, in that the generation of an HIV-specific CTL response has been demonstrated.

With respect to the applicants alleged "admission" that applicants have designed an immunization protocol and the fact that immunization is protection of susceptible individuals from communicable diseases, quoting Steadman's Medical Dictionary, it is submitted that this provides no support for the Examiner's position. It is clear that applicants do not in fact immunize the host, in the sense of protecting the host against HIV infection, but rather, consistent with applicants position, the term is used loosely to convey an administration protocol to achieve the HIV-specific CTL response in the host.

Having regard to the above discussion, it is submitted that claims 1 and 4 to 11 meet the enablement required of 35 USC 112, first paragraph, and the rejection should be withdrawn.

The Examiner maintains provisional rejection of claims 1 and 4 to 11 under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 4 to 11 of copending Application No. 09/647,981.

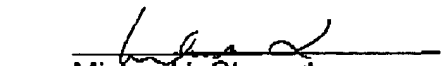
The rejection is a provisional one since the conflicting claims have not yet been patented.

Entry of this Amendment after Final Action is requested, in that the application thereby is placed in condition for allowance. In the event the Examiner considers one or more rejections to be maintained, the Amendment nevertheless should be entered, as the issue with respect to the drawing is corrected thereby.

In the event the Examiner considers that further modification to the claim language is desirable to define the patentable subject matter thereof, the Examiner is requested to call the undersigned, Mr. Michael Stewart, collect, at the number given below, in order to arrive at mutually-acceptable language.

It is believed that this application is now in condition for allowance and early and favourable consideration and allowance are respectfully solicited.

Respectfully submitted,



Michael I. Stewart
Reg. No. 24,973

Toronto, Ontario, Canada,
(416) 595-1155
FAX No. (416) 595-1163